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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,920	06/25/2001	Thomas J. Holman	1001.1181102	9756
28075	7590	06/29/2005	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary

Application No.

09/888,920

Applicant(s)

HOLMAN ET AL.

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-46 is/are pending in the application.
- 4a) Of the above claim(s) 30-34 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 35-39 and 41-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-29, 35-39, 41-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as filed, did not describe a lumen with a fixed (i.e., not able to be changed) diameter along its length nor a lumen having a uniform diameter extending through the connector and strain relief as currently recited in amended claims 27 and 41.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the lumen having a substantially uniform diameter extending through the connector and strain relief, as recited in claim 41 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

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even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 28, 29, 35, 36, 37, 38, 39, 41, 42, 43, 44, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIJKAMP et al. (US Patent No. 5,167,647) in view of LONG et al. (US Patent No. 4,632,488). Wijkamp discloses an integral (i.e., complete unit comprised of parts united to make the whole unit) winged catheter tube hub (fig. 1) including a proximal portion configured as a flange connector 9, a distal portion 5 configured as a strain relief, a lumen extending from the distal end of the hub to a proximal end of the hub being

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substantially fixed (i.e., unchanging during use) and configured to receive a tube 2. The proximal portion is thicker than the distal portion, Wijkamp does not disclose the strain relief to include a generally helical wall separated by spaces that extend into the lumen where the wall thickness and height decreases distally or that the connector is threaded. Wijkamp is silent concerning the materials of construction of the hub. Long discloses a hub comprising a proximal and distal portions having a strain relief with helical wall with bends separated by spaces 30, the helical wall thickness and height decreases distally and extends from near the proximal end to near the distal end. See figs. 3, 5, 11B, 12; col. 5, ll. 1-62. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Long in the device of Wijkamp in order to provide a resilient snug fit having greater resistance to the catheter bending sharply adjacent to the hub.

Re claims 38 and 39 the use of nylon or PEBA in a medical device is a design choice because Applicant has not stated that these materials solve a stated problem or are for a particular purpose and it appears that other materials for medical hubs would work equally as well. Furthermore Applicant has not established any criticality or unexpected results with the use of these materials and one of ordinary skill in the art would have the knowledge to choose from these well-known biomedical materials.

Also re claims 36 and 46 the use of a threaded connector is a design choice with which the skilled artisan could choose between a flange and threaded connector to allow connection to another medical device.

Claims 29, 35, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davila and Klump, Jr. disclose the claimed invention as discussed above, except for the

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decreasing thickness or height of the helical wall strain relief. Lalikos teaches decreasing the thickness and height of strain relief structure to provide a gradual diminishing of the stress relief action (col. 4, lines 23-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Lalikos in the device of Davila and Klump, Jr. in order to have less bending at the proximal end.

Response to Arguments

Applicant's arguments with respect to claims 37-29, 35-39, and 41-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. SUZUKI et al. (U.S. Patent No. 4,682,981) DAVILA, KLUMP, Jr., LALIKOS (US Patent No. 5,143,409), and PRICHARD (US Patent No. 5,380,301) show a hub with strain relief.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
23 June 2005


MICHAEL J. HAYES
PRIMARY EXAMINER